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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,790	10/19/2001	Todd J. Mortier	7528.0003-01	6743

22852 7590 05/21/2008

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ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
05/21/2008	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte TODD J. MORTIER and CYRIL J. SCHWEICH, JR.

Appeal 2008-1502
Application 09/981,790
Technology Center 3700

Decided: May 21, 2008

Before DEMETRA J. MILLS, ERIC GRIMES, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of treating a mitral valve which the Examiner has rejected as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Background

"Dilated cardiomyopathy is often accompanied by mitral valve insufficiency." (Spec. 1). The Specification notes that "as the heart dilates, the positioning of the papillary muscles is altered. Papillary muscles and chordae in a dilated heart will have moved both radially away and down from the mitral valve. This rearrangement of the vascular apparatus and enlargement of the annulus prevent the valve from closing properly" (Spec. 1).

Statement of the Case

The Claims

Claims 64, 66, 67, and 83[1] are on appeal. We will focus on claim 83 which is representative and reads as follows:

> 83. A method of treating an in situ mitral valve, the method comprising: positioning a passive device with respect to a heart such that, throughout the cardiac cycle, a portion of the device contacts and passively alters a geometry of heart structure other than leaflets, chordae, papillary muscles, and an annulus associated with the in situ mitral valve, wherein the passive device draws together leaflets of the in situ valve to promote closure of the in situ valve.

The prior art

The Examiner relies on the following prior art reference to show unpatentability:

Alferness US 5,702,343 Dec. 30, 1997

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[1] Claims 59-62, 68, and 84 are not under appeal, since the Examiner objected to these claims, and did not reject them.

The issues

The rejection as presented by the Examiner is as follows:

Claims 64, 66, 67 and 83 stand rejected under 35 U.S.C. § 102(b), as anticipated by Alferness.

35 U.S.C. § 102(b) anticipation rejection over Alferness

Appellants argue that "Alferness explicitly teaches that the disclosed cardiac reinforcement devices do not provide cardiac assistance during systole" (App. Br. 10). Appellants therefore conclude that "Alferness does not disclose altering the geometry of heart structure throughout the cardiac cycle, as recited in independent claim 83. To the contrary, . . . Alferness explicitly teaches that the disclosed cardiac reinforcement devices act only during diastole and not during systole" (App. Br. 11).

Appellants also contend that "Alferness does not disclose a 'passive device [that] draws together leaflets of [an] in situ valve to promote closure of the in situ valve'" (App. Br. 15). Appellants argue that "[a]t most, Alferness may be interpreted to teach that use of the disclosed cardiac reinforcement devices for constraining cardiac expansion during diastole and preventing cardiac dilation may reduce the naturally occurring consequences of valvular leakage" (App. Br. 15-16).

The Examiner responds regarding the issue of changing heart geometry, that "heart structure is further altered after the device has been adjusted for size reduction" (Ans. 3). The Examiner also argues that "the geometry or configuration of heart wall structure is altered in the sense that significant portions of the heart wall are forced inwardly away from the

parietal pericardium by the reaction forces of the constraining CRD jacket materials and structure" (Ans. 3).

The Examiner contends that "[b]ecause atrioventricular valves are supposed to prevent backflow of blood during systole, the CRD jacket [of Alferness] alters heart structure which in turn reduces the size of the annulus (and hence draws together the leaflets) for the cardiac cycle, including systole" (Ans. 3).

In view of these conflicting positions, we frame the anticipation issues before us as follows:

(1) Does Alferness teach a device which passively alters heart geometry throughout the cardiac cycle?

(2) Does the Alferness device inherently result in drawing the leaflets of the valve together?

Findings of Fact

1. The Specification teaches that the "mitral valve is generally defined as its leaflets or cusps, but in reality, it actually consists of the entire left ventricle chamber" (Spec. 2:16-18).

2. The Specification teaches that in patients with failing hearts, "during the normal cardiac cycle, leaflets 16 may not completely close. Thus, an opening 26 is left between leaflets 16 throughout the cardiac cycle" (Spec. 7:6-9).

3. Alferness teaches that the "invention provides reinforcement of the cardiac wall during diastolic chamber filling to prevent or reduce cardiac dilation in patients known to have experienced such dilation" (Alferness, col. 1, ll. 7-10).

4. Alferness teaches that a "cardiac reinforcement jacket may be applied to the epicardial surface via a minimally invasive procedure" (Alferness, col. 2, ll. 4-5).

5. Alferness teaches that the "biomedical material can be inflexible, but is preferably sufficiently flexible to move with the expansion and contraction of the heart without impairing systolic function" (Alferness, col. 3, ll. 10-14).

6. Alferness teaches that "if one or more of the lateral attachment cords 48 is made of an elastic material, such as silicone rubber, surface pressure exterted on the epicardial surface of the heart varies as a function of the amount of dilation of the heart" (Alferness, col. 7, ll. 4-8).

7. Alferness teaches that "[r]educed cardiac dilation can cause reduction in the problems associated with cardiac dilation such as arrhythmias and valvular leakage" (Alferness, col. 5, ll. 39-41).

Discussion of 35 U.S.C. § 102(b) rejection over Alferness

Alferness teaches a method of treating the heart (FF 3), which involves an interaction with the left ventricle chamber, defined by the Specification as the mitral valve (FF 1). Alferness teaches that a passive device may be positioned on the heart (FF 4). Alferness also teaches that the device contacts the heart and is preferably flexible enough to move with the expansion and contraction of the heart (FF 5), but exerts surface pressure on the heart (FF 6). Finally, Alferness teaches the effect of the device will be reduced valvular leakage (FF 7), where valvular leakage is due to the leaflets failing to completely close (FF 2).

(i) Heart Geometry

The first disputed difference between Alferness and the claim 83 method involves whether the device of Alferness alters a "geometry" of heart structure throughout the cardiac cycle. In analyzing this difference, we first interpret the claims. Neither the term "geometry" nor the phrase "throughout the cardiac cycle" in claim 83 are expressly defined by the Specification. We therefore give these terms their broadest reasonable interpretation consistent with the Specification. *See, e.g., In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) ("[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.").

We interpret the term "throughout the cardiac cycle" as including both systole and diastole, as well as multiple cycles of heartbeat, since the Specification indicates that during the cardiac cycle, the mitral valve should both open and close (*see* FF 2). We interpret the term "geometry" broadly, as encompassing as any alteration in the heart structure.

Applying these interpretations to the claims, we think the Examiner reasonably concludes that some alteration of the geometry of the heart is inherently imposed by a flexible device that permits expansion and contraction of the heart (*see* FF 5-6). We also agree with the Examiner that where the Alferness CRD jacket functions to reduce the amount of cardiac dilation over an extended period of time, that will inherently result in alteration of the heart geometry in systole as well as diastole (*see* Ans. 3).

> [I]t is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those

> things to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

In re Best, 562 F.2d 1252, 1254-1255 (CCPA 1977) (*quoting In re Swinehart*, 439 F.2d 210, 212-13 (CCPA 1971)). There is no dispute that the device alters the geometry of the heart by limiting movement during the expansion of the heart in diastole (*see* FF 3) and that this alteration treats the cardiac dilation.

Alferness expressly states that the material in the cardiac reinforcement device must be "sufficiently flexible to move with the expansion and contraction of the heart without impairing systolic function" (Alferness, col. 3, ll. 10-14). We think this Alferness statement reasonably teaches that the device will necessarily move with the contracting heart in systole, and the presence of a partially flexible reinforcement jacket in the pericardium that is contracting along with the heart during systole can reasonably be expected to impact heart geometry.

We are not persuaded by Appellants' argument that "the Examiner has not established that Alferness's disclosure of placing a cardiac reinforcement jacket under the parietal pericardium is necessarily a teaching of altering a gemoetry of heart structure throughout the cardiac cycle" (App. Br. 12). Appellants concede that the device "lies essentially flush with heart surface" (App. Br. 13). Such a device, flush with the heart surface and flexible to

move during both expansion and contraction, will necessarily alter the heart structure (FF 5-6). Additionally, as the dilation of the heart is treated and cardiac size is reduced, the geometry of the heart will inherently change during systole as well as diastole. Appellants have provided no evidence that the device will not affect heart geometry and have therefore not satisfied the burden of production imposed under *Best*.

(ii) Valve leaflets

Appellants also argue that Alferness does "not disclose or otherwise suggest a device that acts on the valve or draws together leaflets to close the valve" (App. Br. 15).

This argument is not persuasive because the Specification teaches that the valve leaflets remain open in failing hearts (FF 2) and Alferness discloses that the device can cause a reduction in valvular leakage (*see* FF 7). In order for Alferness to function to reduce leakage through the valve, the device must promote closure of a valve, resulting in the leaflets inherently being drawn more closely together (*see* FF 7). Whether the Alferness device promotes closure via a reduction in the size of the heart, a reduction in annulus size, or a direct effect of the sleeve during diastole is immaterial since the effect is inherent in the reduction in valvular leakage. "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 919 F. 2d 1575, 1578 (Fed. Cir. 1990).

We are not persuaded by Appellants' argument that "since Alferness discloses devices that provide cardiac reinforcement only during diastole, . . . it is counterintuitive for the Alferness devices to 'draw together leaflets of

[an] in situ valve to promote closure of the in situ valve' during diastolic filling" (App. Br. 17).

However, Appellants' Specification states that "as the failing heart has dilated, papillary muscle 12 has been drawn away from mitral valve 14. The chordae connections between papillary muscles 12 and valve 14 in turn draws leaflets 16 apart such that during normal cardiac cycle, leaflets 16 may not completely close" (Spec. 7:3-7). Since, Alferness teaches that the use of the device results in a reduction in cardiac dilation (FF 3), and since Appellants' Specification contends that cardiac dilation causes the leaflets to remain open, the Examiner reasonably concludes that treatment of cardiac dilation will also serve to promote closure of the valve (*see* Ans. 3), consistent with the discussion in Appellants' Specification.

We affirm the rejection of claim 83 as anticipated by Alferness. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 64, 66, and 67 as these claims were not argued separately.

CONCLUSION

In summary, we affirm the rejection of claim 83 under 35 U.S.C. § 102(b). Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 64, 66, and 67 as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

Ssc:

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